ISO/DIS 17025 – GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

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Introduction

This International Standard has been produced as the result of extensive experience of the implementation of ISO/IEC Guide 25: 1990 and EN 45001 :1989 both of which it now replaces. It contains all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

Accreditation bodies that recognize the competence of testing and calibration laboratories will use this International Standard as the basis for their accreditation. Clause 4 specifies the requirements that a laboratory has to meet in order to demonstrate that it has sound management. Clause 5 specifies the requirements in order to demonstrate technical competence for the type of tests and/or calibrations it undertakes.

The growth in use of quality systems generally has increased the need to ensure that laboratories that form part of larger organizations or offer other services can operate to a quality system that is seen as compliant with ISO 9001 or ISO 9002 as well as with this International Standard. Care has been taken, therefore, to incorporate all of those requirements of ISO 9001 and ISO 9002 that are relevant to the scope of testing and calibration services that are covered by the laboratory's quality system.

Testing and calibration laboratories that comply with this International Standard also operate in accordance with ISO 9001 or ISO 9002 and are able to implement a single quality system meeting the requirements of both this International Standard and ISO 9001-2 if they so wish.

It should be noted, however, that laboratories that only obtain certification to ISO 9001 or ISO 9002 will not be able to demonstrate that they are technically competent and can produce technically valid testing and/or calibration results. On the other hand, accreditation is not the same as being certified against ISO 9001 or ISO 9002.

The acceptance of testing and calibration results between countries will be facilitated if laboratories comply with this International Standard and if they obtain accreditation from bodies who have entered into mutual recognition agreements with equivalent bodies in other countries using this International Standard.

The use of this International Standard will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, and in the harmonization of standards and procedures.

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General Requirements for the Competence of Testing and Calibration Laboratories

1 Scope

1.1 This International Standard specifies the general requirements a laboratory has to meet if it is to be recognized as competent to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standardized methods, methods not covered by standardized methods, and laboratory-developed methods.

1.2 This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example, first-party, second-party and third- party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

This International Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by this International Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

1.3 The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this International Standard.

1.4 This International Standard is for use by laboratories in developing their quality, administrative and technical systems that govern their operations. It can also be used by laboratory clients, regulatory authorities and accreditation bodies involved in confirming or recognizing the competence of laboratories.

1.5 If testing and calibration laboratories comply with the requirements of this International Standard they will operate a quality system for their testing and calibration activities that also meets the requirements of ISO 9001 when they engage in the design/development of new methods, and ISO 9002 when they only use standardized methods. Annex A provides cross-references between this International Standard and ISO 9001 and ISO 9002. Compliance with the requirements of clauses 4 and 5 means that the laboratory also complies with the requirements of ISO 9001 or ISO 9002.

1.6 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.

NOTE 1 It might be necessary to explain or interpret certain requirements in this International Standard to ensure that the requirements are applied in a consistent manner. Guidance for establishing specific requirements is given in annex B.

NOTE 2 If a laboratory wishes accreditation for part or all of its testing and calibration activities, it should select an accreditation body that operates in accordance with ISO/IEC Guide 58.

NOTE 3 This International Standard does not cover compliance of the activities of a

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laboratory with the relevant regulatory and safety requirements which are not included in the scope of the laboratory.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO/IEC Guide 2, *General terms and their definitions concerning standardization and related activities.*

VIM: 1993, *International vocabulary of basic and general terms in metrology*, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.

ISO 9001: 1994, Quality systems - Model for quality assurance in design, development, production, installation and servicing.

ISO 9002: 1994, Quality systems - Model for quality assurance in production, installation and servicing.

NOTE Further related standards, guides, etc. on subjects included in this International Standard are given in the bibliography.

3 Terms and definitions

For the purposes of this International Standard, the relevant definitions given in ISO/IEC Guide 2 and VIM, and the following terms and definitions apply.

NOTE ISO 8402 sets out the general definitions related to quality whereas ISO/IEC Guide 2 sets out the definitions specifically related to standardization, certification and laboratory accreditation. Where different definitions are given in these publications, the definitions in ISO/IEC Guide 2 and VIM are preferred.

3.1
best measurement capability:
smallest uncertainty of measurement that a calibration laboratory can achieve for a stated calibration or type of calibration, when performing more or less routine calibrations of nearly ideal measurement devices

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4 Management requirements

4.1 Organization and management

4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

4.1.2 The laboratory shall be organized and shall operate in such a way that it meets the requirements of this International Standard whether carrying out work in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.3 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

NOTE Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financial should not adversely influence the laboratory's compliance with the requirements of this International Standard.

4.1.4 The laboratory shall

a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic transmission of results;

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define, with the aid of organizational charts, the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations, support services and the quality system;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) provide adequate supervision of testing and calibration staff, including trainees, by persons

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familiar with the test and/or calibration methods and procedures, with the purpose of each test and/or calibration, and with the assessment of the test or calibration results;

h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources;

j) appoint deputies for key managerial personnel such as the quality manager (see note 3).

NOTE 1 Legal or other requirements may specify that the laboratory be a third-party laboratory.

NOTE 2 A laboratory wishing to be recognized as a third-party laboratory may need to produce documentary evidence to show clients and other interested parties that it is not subjected to any influence that may adversely effect its independence and impartiality.

NOTE 3 In laboratories with a small number of personnel, individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.2 Quality system

4.2.1 The laboratory management shall establish, implement and maintain a quality system appropriate to the scope of its activities, including the type, range and volume of testing and/or calibration activities it undertakes. The laboratory management shall document its policies, systems, programmes, procedures and instructions to the extent necessary to enable the laboratory to assure the quality of the test and/or calibration results it generates. Documentation used in this quality system shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 The laboratory management shall define and document its policies and objectives to be achieved by implementing the quality system. The laboratory management shall ensure that these policies and objectives are documented in a quality manual. The overall objectives shall be set out in a quality policy statement in the quality manual stating the standard of performance to be obtained and maintained. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

a) a statement of the laboratory management's intentions with respect to the standard of service it will provide;

b) the purpose of the quality system;

c) a requirement that all personnel concerned with testing and calibration activities within the

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laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work;

d) the laboratory management's commitment to good professional practice and quality of its testing and calibration in servicing its client; and

e) the laboratory management's commitment to compliance with this International Standard.

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated standardized methods and clients' requirements.

4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system. The quality manual shall be maintained up to date.

4.2.4 The quality manual shall define the roles and responsibilities of technical management and the quality manager including their responsibility for ensuring compliance with this International Standard

4.3 Document control

4.3.1 General

The laboratory shall establish and maintain procedures to control all documents (internally generated and from external sources) that form part of its quality documentation. These include documents of external origin, such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, specifications, instructions and manuals.

NOTE 1 In this context "document" means any information or instructions including policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.8.

4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

a) authorized editions of appropriate documents are available at all locations where operations

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essential to the effective functioning of the laboratory are performed;

b) documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, the total number of pages or a mark to signify the end of the document, and the authority for issue.

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

4.3.3.3 If the laboratory's documentation control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialled and dated. A revised document shall be formally re-issued as soon as practicable.

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of request, tender or contract

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders or contracts. The policies and procedures for the review of each contract, request or tender leading to a contract for testing and/or calibration shall ensure that:

a) the requirements including the methods to be used are adequately defined, documented and understood (see 5.4.2);

b) the laboratory has the capability and resources to meet the requirements;

c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements.

Any differences between the request or tender and the contract shall be resolved before any work

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commences. Each contract shall be acceptable both to the laboratory and the client.

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programmes using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract may be any written or oral agreement to provide a client with testing and/or calibration services.

4.4.2 Records of such reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

NOTE For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on grant of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

4.4.4 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

4.5 Subcontracting of tests and calibrations

4.5.1 When a laboratory has to subcontract work (e.g. because of unforeseen circumstances, workload, large contracts or contracts requiring some extra technical expertise), this shall be placed with a competent subcontractor.

4.5.2 The laboratory shall advise and obtain approval from the client, preferably in writing, when the laboratory intends to subcontract to another laboratory specific tests and/or calibrations, or a part of a test and/or calibration.

4.5.3 The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the requirements of this International Standard for the work being subcontracted.

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NOTE There may be circumstances where the client specifies which subcontractor is to be used by the laboratory. In such cases the laboratory may not be able to demonstrate the competence of the subcontractor and therefore is not responsible for the results.

4.5.4 The laboratory is always responsible to its client for the work the subcontractor performs.

4.5.5 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the assessments it has made of them and of all subcontracted tests and/or calibrations.

4.6 Purchasing services and supplies

4.6.1 The laboratory shall have policies and procedures for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of consumable materials relevant for the tests and calibrations.

4.6.2 The laboratory shall use only such services and supplies that are of the quality needed to sustain confidence in the results of tests and/or calibrations. Services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 Purchasing documents, for items affecting the quality of laboratory output, shall contain data describing the product ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, quality required and quality system standard under which they were made.

4.6.4 The laboratory shall ensure that purchased supplies and consumable materials that affect the quality are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned.

4.6.5 The laboratory shall evaluate suppliers of critical services which affect the quality of testing and maintain records of these evaluations and list those approved.

4.7 Service to the client

The laboratory shall afford clients or their representatives cooperation to facilitate clarification of the client's request and to monitor the performance of the laboratory in relation to the work performed.

NOTE 1 Such cooperation may include:
a) affording the client or the client's representative reasonable access to relevant areas of the

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laboratory for the witnessing of tests and/or calibrations performed for the client; it is understood that such access should not conflict with rules of confidentiality of work for other clients or with safety;
b) preparation, packaging, and dispatch of test and/or calibration items needed by the client for verification purposes.

NOTE 2 Clients value the maintenance of good contacts, advice and guidance in technical matters, and opinions and interpretations based on results. Contact with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests and/or calibrations.

NOTE 3 Laboratories are encouraged to obtain other feedback, both positive and negative, from their clients (e.g. client surveys). The feedback should be used to improve the quality system, testing and calibration activities and client service.

4.8 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.10).

4.9 Control of nonconforming testing and/or calibration work

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform with its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that:

a) responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, the results of nonconforming work already released to clients are recalled;

e) the responsibility for authorizing the resumption of work is defined.

NOTE Identification of nonconforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations such as customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

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4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.10 shall be promptly followed to identify the root cause(s) of the problem and to eliminate this (these) cause(s).

4.10 Corrective action

4.10.1 General

The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

The laboratory shall document and implement any required changes to the operational procedures resulting from corrective action investigations.

NOTE A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from clients or staff observations.

4.10.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE 1 Cause analysis is the key and sometimes the most difficult part in the corrective action procedure.

NOTE 2 Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include client requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumable materials, or equipment and its calibration.

4.10.3 Corrective actions

Having identified the cause(s), the laboratory shall identify the potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Any corrective action taken to eliminate the cause(s) of nonconformances or other departures shall be to a degree appropriate to the magnitude of the problem and commensurate with the risks encountered.

4.10.4 Monitoring of corrective actions

After having implemented the corrective action(s), the laboratory shall monitor the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

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4.10.5 Special audits

Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are promptly audited in accordance with 4.13.

NOTE Such special audits often follow the implementation of the corrective actions to confirm their effectiveness. A special audit should only be necessary when a serious issue or risk to the business is identified.

4.11 Preventive action

4.11.1 Opportunities for needed improvement and potential sources of nonconformances, either technical or with the quality system, shall be identified. If action is required, action plans shall be developed, implemented and monitored, to reduce the likelihood of occurrence of such nonconformances and to take advantage of the improvement opportunities.

4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

NOTE 1 Preventive action is a pro-active process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend analysis, analysis of proficiency testing results and risk analysis.

4.12 Records

4.12.1 General

4.12.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as corrective and preventive action records.

4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

NOTE Records may be in the form of any type of media, such as hard copy or electronic media.

4.12.1.3 All records shall be held secure and in confidence.

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4.12.1.4 The laboratory shall have procedures to protect and back-up data held on computers at all times and to prevent unauthorized access to or amendment of data on computers.

4.12.2 Technical records

4.12.2.1 The laboratory shall retain original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for sampling, performance of each test and/or calibration and checking of results.

NOTE Technical records are accumulations of data and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, test reports, calibration certificates, clients' notes, papers and feedback, test reports and calibration certificates to clients.

4.12.2.2 Observations, data and calculations shall be clearly and permanently recorded and identifiable to the specific job at the time they are made.

4.12.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible nor deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of computer-collected data, similar measures shall be taken to avoid loss or change of original data.

4.13 Internal audits

4.13.1 The laboratory shall periodically and in accordance with a predetermined schedule and procedure conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit programme shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out (see also 4.10.5).

NOTE The cycle for internal auditing should normally be completed in one year.

4.13.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results may have been affected.

4.13.3 The area of activity audited, the audit findings and corrective actions that arise from them

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shall be recorded. The laboratory management shall ensure that these corrective actions are discharged within an appropriate and agreed timescale.

4.14 Management reviews

4.14.1 The management of the laboratory with executive responsibility shall, periodically and in accordance with a predetermined schedule and procedure, conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review shall take account of reports from managerial and supervisory personnel, the outcome of recent internal audits, and corrective and preventive actions, assessments by external bodies, the results of interlaboratory comparisons or proficiency tests, any changes in the volume and type of the work undertaken, feedback from clients, including complaints and other relevant factors, such as quality control facilities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months. Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 2 A management review can be supplemented by consideration of related subjects at regular management meetings.

4.14.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed timescale.

5 Technical requirements

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- human factors (5.2),
- accommodation and environmental conditions (5.3),
- test and calibration methods and method validation (5.4),
- equipment (5.5),
- measurement traceability (5.6),
- sampling (5.7),
- handling of test and calibration items (5.8).

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

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5.2 Personnel

5.2.1 The laboratory management shall ensure the competency of all who operate specific equipment, who perform tests and/or calibrations, evaluate results and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

NOTE In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, might be included in the standards for the specific technical field, or required by the client.

5.2.2 The management of the laboratory shall formulate the goals with respect to the education and the skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to present and anticipated tasks of the laboratory.

5.2.3 The laboratory shall use personnel who are permanently employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.

5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

NOTE Job descriptions can be defined in many ways. As a minimum, the responsibilities with respect to the following should be defined:

- performing tests and/or calibrations;
- planning of tests and/or calibrations and evaluation of results;
- method modification and development and validation of new methods;
- expertise and experience;
- qualifications and training programmes;
- managerial duties.

5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant competence, educational and professional qualifications, training, skills and experience of all technical personnel, contracted personnel included. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed and the criteria on which the authorization is based and the confirming authority.

5.3 Accommodation and environmental conditions

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5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of tests and/or calibrations.

The laboratory shall ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling, tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by relevant specifications or where they may influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

5.3.3 There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled.

5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.4 Test and calibration methods including sampling

5.4.1 General

The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope, including sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained current and be made readily available to personnel. Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized and accepted by the client.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. Consideration may need to be given to providing additional documentation for optional steps in

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the method or additional details.

5.4.2 Selection of methods

The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes preferably those published as international, regional or national standards. The laboratory shall ensure that it uses the latest edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

When the client does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standardized methods before introducing the tests or calibrations. If the standardized method changes, the confirmation shall be repeated.

The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out-of date.

5.4.3 Laboratory-developed methods

Introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and be assigned to qualified personnel equipped with adequate resources.

Plans shall be updated as development proceeds and shall ensure effective communication amongst all personnel involved.

5.4.4 Non-standardized methods

When it is necessary to employ methods not covered by standardized methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use, and be available for examination by the client and other authorized recipients.

NOTE New test and/or calibration methods and procedures should be produced prior to the tests and/or calibrations being performed and should contain at least the following information:

a) scope;
b) description of the type of item to be tested or calibrated;
c) parameters or quantities to be determined;
d) apparatus, equipment, reference standards and reference materials required;
e) environmental conditions required and any stabilization period needed;
f) description of the procedure, including

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- affixing identification marks, handling, transporting, storing and preparing of items,
- checks to be made before the work is started,
- checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use,
- method of recording the observations and results,
- any safety measures to be observed;

g) criteria and/or requirements for approval/rejection;

h) data to be recorded and method of analysis and presentation;

i) uncertainty or procedure for estimating uncertainty.

5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of effective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 The laboratory shall validate non-standardized methods, laboratory- designed/developed methods, standardized methods used outside their intended range and amplifications of standardized methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs in the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use shall be relevant to the clients' needs.

NOTE 1 Validation includes the specification of the requirements, determination of the characteristics of the methods, the comparison of the requirements with the values of the characteristics of the method, and a statement on the validity.

NOTE 2 The techniques used for the determination of the characteristics of a method should be one of, or a combination of, the following: calibration using reference standards or reference materials, comparison of results achieved with other methods, interlaboratory comparisons, systematic assessment of the factors influencing the result, assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 As method development proceeds, regular review is required to verify that the needs of the client are still being fulfilled. Changing requirements requiring modifications to the development plan should be approved and authorized.

NOTE 4 Validation is always a balance between costs, risks and technical possibilities.

5.4.6 Best measurement capability

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5.4.6.1 A calibration laboratory shall have procedures to calculate its best measurement capability. These calculations shall be available for specified ranges and for all quantities/measurements in its scope.

NOTE The actual uncertainty of measurement is normally larger than the best measurement capability due to the non-ideal behaviour of the calibrated item.

5.4.7 Estimation uncertainty of measurement

5.4.7.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and apply a procedure to estimate the uncertainty of measurement for all calibrations and for all types of calibrations.

5.4.7.2 Testing laboratories shall also have and apply procedures for estimating uncertainties of measurement, except when the test methods preclude such rigorous calculations. In certain cases it is not possible to undertake metrologically and statistically valid estimations of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy.

NOTE In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the reporting instructions.

5.4.7.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using accepted methods of analysis.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the condition of the item being tested or calibrated and the operator.

NOTE 2 The predicted long-term behaviour of the tested and/or calibrated item is normally not taken into account when estimating the measurement uncertainty.

NOTE 3 For further information see ISO 5725-1 and the Guide to the Expression of Uncertainty in Measurement (see bibliography).

5.4.8 Control of data

5.4.8.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.8.2 When computers or automated equipment are used for the acquisition, processing,

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recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use;

b) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE Commercial software in general use within its designed application range may be considered sufficiently validated.

5.5 Equipment

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met (see 4.6).

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant affect on the results. When received, equipment, including that used for sampling, shall be checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and shall be checked and/or calibrated in accordance with 5.6 before use.

5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

5.5.4 Each item of equipment used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

5.5.5 Records shall be maintained of each item of equipment significant to the tests and/or calibrations performed. The records shall include at least the following:

a) identity of the item of equipment;

b) manufacturer's name, type identification, and serial number or other unique identification;

c) checks that equipment complies with the specification (see 5.5.2);

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d) current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration;

g) maintenance carried out to date and the maintenance plan;

h) damage, malfunction, modification or repair to the equipment.

5.5.6 The laboratory shall have procedures and have an established plan for safe handling, transport, storage, use and maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

5.5.7 Maintenance procedures shall be established.

5.5.8 Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service, clearly labelled or marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure.

5.5.9 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration and the date when recalibration is due.

5.5.10 When, for whatever reason, equipment goes outside the direct control of the laboratory for a period, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.11 When computers or automated test or calibration equipment are used for the collection, processing, recording, reporting, storage or retrieval of test and/or calibration data, the laboratory shall ensure that the requirements of 5.4.8 are met.

5.5.12 When checks are needed to maintain confidence in the calibration status of the equipment these checks shall be carried out periodically according to a defined procedure.

5.5.13 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that any copies (e.g. in computer software) are correctly updated.

5.5.14 Test and calibration equipment, including both hardware and software, shall be safeguarded

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from adjustments which would invalidate the test and/or calibration results.

5.6 Measurement traceability

5.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.

NOTE Such a programme should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference standards used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

5.6.2 Specific requirements

5.6.2.1 Calibration

For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the SI (Système International) units of measurement.

Traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall show that there is a link to a primary standard or to a natural constant realizing the SI unit by an unbroken chain of calibrations. The calibration certificates shall contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

NOTE 1 Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

NOTE 3 The term "identified metrological specification" means that it must be clear from the calibration certificate against which specification the measurements have been compared by including the specification or by giving an unambiguous reference to the specification.

NOTE 4 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

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5.6.2.2 Testing

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that equipment used can provide the accuracy of measurement needed.

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used, as given in 5.6.2.2.2.

5.6.2.2.2 Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results shall be applied such as:

a) the use of suitable reference materials certified to give a reliable characterization of the material;

b) mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned;

c) participation in a suitable programme of interlaboratory comparisons or proficiency testing.

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

5.6.3.2 Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

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5.6.3.4 Transport and storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

5.7 Sampling

5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, matrices, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure and shall be available at the location where sampling is undertaken.

NOTE 1 Sampling is a defined procedure whereby a part of a substance, matrix, material or product is taken to provide for testing or calibration a representative sample of the whole. Sampling can also be required by the appropriate specification for which the substance, matrix, material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative but determined by availability.

NOTE 2 A sampling plan should describe the allocation, withdrawal and preparation of a sample or samples from a substance, matrix, material or product to yield the required information.

5.7.2 Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and included in all

documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and the diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

5.8 Handling and transportation of test and calibration items

5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item.

5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be

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designed and operated so as to ensure that items cannot be confused physically, or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

5.8.3 Upon receipt of the test or calibration item, any abnormalities or departures from normal or specified conditions, as described in the relevant test or calibration method, shall be recorded. When there is any doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion.

5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation; instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or portion of an item is to be held secure (e.g. for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later), the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

NOTE 1 Where test items are to be returned into service after testing (e.g. for non-destructive testing or human beings subject to medical tests), special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling plan and information on storage and transport of samples, including all information which may influence the test or calibration result, should be provided to those responsible for taking and transporting the samples.

5.9 Assuring the quality of test and calibration results

The laboratory shall ensure the quality of results by monitoring test and/or calibration results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following

a) internal quality control schemes using statistical techniques;

b) participation in interlaboratory comparison or proficiency testing programmes;

c) regular use of certified reference materials and/or internal quality control using secondary reference materials;

d) replicate tests or calibrations using the same or different methods;

e) re-testing or re-calibration of retained items;

f) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work

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undertaken.

5.10 Reporting the results

5.10.1 General

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results shall be reported, normally in a test report or a calibration certificate (see note 1) and shall include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, 5.10.3 and 5.10.4.

In the case of tests or calibrations performed for internal clients, and in the case of a written agreement with the client, the results may be reported in a simplified way. The information listed in 5.10.2 to 5.10.4, and not reported, shall be readily available in the laboratory which carried out the tests and/or calibrations.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.

5.10.2 Test reports and calibration certificates

5.10.2.1 Subclause 5.10.2.2 contains the requirements for both test reports and calibration certificates. Additional specific requirements for test reports and calibration certificates are included in 5.10.3 and 5.10.4, respectively.

5.10.2.2 Unless the laboratory has exceptional reasons for not doing so, each test report or calibration certificate shall include at least the following information:

a) a title (e.g. "Test Report" or "Calibration Certificate");

b) name and address of laboratory, and location where the tests and/or calibrations were carried out if different from the address of the laboratory;

c) unique identification of the test report or calibration certificate (such as serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;

d) name and address of the client placing the order;

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e) description and unambiguous identification of the item(s) tested or calibrated;

f) date of receipt of test or calibration item(s) and date(s) of performance of the test or calibration where relevant to the validity and application of the results;

g) test or calibration results with units of measurement;

h) reference to sampling procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;

i) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

j) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

NOTE Laboratories are recommended to include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2.2, test reports shall, where necessary for the interpretation of the test results, include:

a) description and condition of the test item(s);

b) identification of the standardized test method(s) used, or unambiguous brief description of any non-standardized method used;

c) identification of the standard(s) or specification(s) relevant to the test;

d) deviations from, additions to or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

e) where relevant, a statement of compliance/non compliance with requirements and/or specifications;

f) where appropriate and needed opinions and interpretations see (5.10.5);

g) where applicable, a statement on the estimated uncertainty of measurement of the test result; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when uncertainty affects compliance to a specification limit;

h) additional information required by specific branches.

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5.10.3.2 In addition to the requirements listed in 5.10.2.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

a) date of sampling;

b) unambiguous identification of substance, matrix, material or product sampled (including name of manufacturer, model or type of designation and serial numbers as appropriate);

c) location of sampling, including any diagrams, sketches or photographs;

d) reference to sampling plan used;

e) details of any environmental condition during sampling that may affect the interpretation of the test results;

f) identification of the sampling method or procedure used;

g) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

a) an identification of the standard specification used or a brief unambiguous description of the method;

b) the conditions (e.g. environmental) under which the calibrations were made;

c) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

d) evidence that the measurements are traceable.

5.10.4.2 The calibration certificate shall relate only to metrological quantities and the results of functional tests and shall specifically state which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

When statements of compliance are made, the uncertainty of measurement shall be taken into account.

NOTE When an instrument for calibration has been adjusted or repaired, the calibration

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results before adjustment of repair, if available, should be reported.

5.10.4.3 A calibration certificate (or calibration label) shall not contain any recommendation on the recalibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.5 Opinions and interpretations

When opinions and interpretations are included in the test report, the laboratory shall be able to show that it has documented the basis upon which the opinions and interpretations have been made.

NOTE 1 Opinions and interpretations should not be mixed-up with inspections and product certifications as intended in ISO/IEC Guides 39 and 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited, to the following:
- opinion on conformity of the results with requirements;
- fulfilment of contractual requirements;
- recommendations on how to use the results;
- guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the client.

5.10.6 Testing and calibration results obtained from subcontractors

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contractor.

5.10.7 Electronic transmission of results

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.8).

5.10.8 Format of reports and certificates

The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

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NOTE 2 The headings should be standardized as far as possible.

5.10.9 Amendments to test reports and calibration certificates

Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Supplement to Test Report [or Calibration Certificate], serial number...[or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this International Standard.

When it is necessary to issue a complete new test report or calibration certificate, it shall be uniquely identified and shall contain a reference to the original that it replaces.

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Annex A

(informative)

Cross-references to ISO 9001:1994 and ISO 9002:1994

ISO 9001:1994	ISO 9002:1994	ISO 17025
1	1	1
2	2	2
3	3	3
4.1.1	4.1.1	4.2.2
4.1.2.1	4.1.2.1	4.1.4 f), h) and 5.2.4
4.1.2.2	4.1.2.2	4.1.4 h) and 5.5.3 and 4.13.1
4.1.2.3	4.1.2.3	4.1.4 i)
4.1.3	4.1.3	4.14
4.2.1 to 4.2.2	4.2.1 to 4.2.2	4.2.1 to 4.2.3
4.2.3	4.2.3	4.2.1 (in part) and 4.12.1.1 and 5.4
4.3	4.3	4.4
4.4	4.4	5.4.2 to 5.4.5
4.5	4.5	4.3 and 5.4.8
4.6.1	4.6.1	4.6 and 5.5.1
4.6.2	4.6.2	4.5
4.6.3	4.6.3	4.6
4.6.4	4.6.4	4.5 and 4.6 and 5.5.2
4.7	4.7	5.8
4.8	4.8	5.8
4.9	4.9	5.1 to 5.3 and 5.9
4.10.1	4.10.1	5.4
4.10.2	4.10.2	4.6 and 5.5.2 and 5.8.1 to 5.8.1.3
4.10.3	4.10.3	5.8.4
4.10.4	4.10.4	5.4.8 and 5.9 and 5.10.2.1 i)

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4.10.5	4.10.5	4.12.2

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4.11.1	4.11.1	5.4 to 5.6
4.11..2 a)	4.11.2 a)	5.4.1 and 5.4.5.1 and 5.5.2
4.11.2 b)	4.11.2 b)	5.5.2 and 5.6
4.11.2 c)	4.11.2 c)	5.5.2 and 5.5.6 and 5.5.12
4.11.2 d)	4.11.2 d)	5.5.9
4.11.2 e)	4.11.2 e)	5.5.4
4.11.2 f)	4.11.2 f)	5.5.6 and 5.5.7
4.11.2 g)	4.11.2 g)	5.3
4.11.2 h)	4.11.2 h)	5.5.6 and 5.6.3.4 and 5.8
4.11.2 i)	4.11.2 i)	5.5.6
4.12	4.12	5.10.3.1 e) and 5.10.4.1 c)
4.13	4.13	4.9
4.14.1	4.14.1	4.10 and 4.11
4.14.2	4.14.2	4.10
4.14.3	4.14.3	4.11
4.15	4.15	5.8
4.16	4.16	4.12
4.17	4.17	4.12/13
4.18	4.18	5.2.1 to 5.2.3 and 5.2.5 (in part) and 5.5.3
4.19	4.19	not applicable
4.20	4.20	5.9

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Annex B

(informative)

Guidelines for establishing specific requirements for laboratory competence

B.1 The requirements specified in this International Standard are stated in general terms and, while they are applicable to all test and calibration laboratories, amplification might be needed. Such amplifications are herein referred to as specific requirements.

B.2 Specific requirements can be thought of as an elaboration or interpretation of the generally stated criteria (requirements) of this International Standard for certain field of tests and calibrations, test technologies, products, materials or specific tests or calibrations. Accordingly, specific requirements shall be established by persons having appropriate technical knowledge and experience, and shall address items that are essential or most important for the proper conduct of a test or calibration. Specific requirements should not include new or additional general requirements not included in this International Standard.

B.3 Depending on the application at hand, it may be necessary to establish specific requirements for the technical requirements of this International Standard. Establishing specific requirements may be accomplished by simply interpreting or adding extra information to the already generally stated requirements in each of the clauses (e.g. specific limitations to the temperature and humidity in the laboratory).

In some cases the specific requirements will be quite limited, applying only to a given test or calibration method or to a group of calibration or test methods. In other cases the specific requirements may be quite broad, applying to the testing or calibration of various products or items or to entire fields of testing or calibration.

B.4 If the specific requirements apply to a group of test or calibration methods in an entire technical field, common language can be used for all of the methods.

Alternatively, one may wish to develop a separate document of specific requirements to supplement this International Standard for specific types or groups of tests or calibrations, products, materials or technical fields of tests or calibrations. Such a document should provide only the necessary supplementary information, maintaining this International Standard as the governing document through reference. Too specific amplifications or interpretations should be avoided in order to limit the proliferation of detailed documents.

B.5 The guidance in this annex should be used by accreditation bodies, or other types of evaluation bodies, when developing specific requirements for their own purposes (e.g. accreditation in specific areas).

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